

Testi10™ Saline-Filled Testicular Prosthesis FILLING INSTRUCTIONS

Testi10™ Saline-filled Testicular Prosthesis is supplied in a sealed, double-pouch and inside a protective carton box.

Supplies needed for filling, not supplied by Rigicon

- ♂ Sterile, isotonic, pyrogen-free Sodium Chloride U.S.P. solution
- ♂ 27 Gauge Needle
- ♂ 5 cc syringe



PRECAUTIONS

Use only a sterile 27 Gauge needle.

Insert the needle carefully through the injection port (where the suture tab is) as close to the center of the port.

The needle can only be inserted into the injection port in a gentle manner to eliminate the risk of puncturing the inner walls of the prosthesis.

Do not insert the needle in any location other than the injection port as it will puncture the prosthesis.

Do not use the prosthesis if it is punctured in any location other than the injection port.

Do not squeeze the prosthesis while the needle is inserted and do not try to evacuate air from the prosthesis.

Testi10™ Saline-Filled Testicular Prosthesis				
Product Code	Size	Volume	A (cm)	B (cm)
TESTISF-XS	Extra small	6 ml	2.7	2.1
TESTISF-S	Small	12 ml	3.2	2.6
TESTISF-M	Medium	18 ml	4.1	2.9
TESTISF-L	Large	22 ml	4.7	3.2
TESTISF-XL	Extra Large	26 ml	5.1	3.2

FILLING INSTRUCTIONS

Step 1. Fill 5cc (or larger) syringe with sterile, isotonic, pyrogen-free Sodium Chloride U.S.P. solution

Step 2. Insert the needle into the injection port of the prosthesis (the circle around the suture tab) (See Figure 1)

Step 3. Hold the testicular prosthesis with the injection port at the top and position the syringe in a manner to enable the air inside the prosthesis will travel into the syringe.

Step 4. Slowly inject the saline into the prosthesis. While injecting saline, release the syringe plunger at intervals to allow air to be drawn into the syringe. Repeat this cycle until remaining air travels into the syringe. Keep the needle inside the injection port while refilling the syringe.

Step 5. Stop injecting saline when the desired firmness is achieved. Refer to recommended fill volume chart over-page. The prosthesis can be under filled or up to +10% of the recommended fill volume.

SUTURE TAB

The prosthesis may be secured through the suture tab. Suturing the prosthesis in any area other than the suture tab will damage the prosthesis and result in fluid leakage. Take care not to pierce the prosthesis.

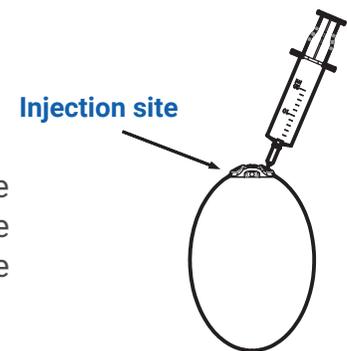


Figure 1

RIGI10-06-03.2020- Rigicon, Inc.

Caution: Federal Law (U.S.) restricts this device to sale by or on the order of a physician.

Refer to Instructions for Use for a complete listing of indications, contraindications, warnings, precautions and potential adverse events.

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